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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,904

08/22/2003

Herbert Irschik

103832-510-NP

1332

24964 7590 10/04/2007

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

10/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/646,904

Applicant(s)

HERBERT IRSCHIK

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/30/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-14 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-14 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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Non-Final Office Action

Claims 1-5, 9-14 and 18 are pending. No claim is allowed at this time.

Amendments are entered.

Summary of this Office Action dated Sunday, September 30, 2007

1. Continued Examination Under 37 CFR 1.114
2. Information Disclosure Statement
3. Copending Applications
4. Specification
5. 35 USC § 112 --- First Paragraph Written Description Rejection
6. Response to Remarks
7. Communication

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/30/2007 has been entered.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to

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patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

35 USC § 112 --- First Paragraph Written Description Rejection

1. Claims 1–5, 9-14 and 18 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Following reasons apply.

Furthermore, the written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The

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function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.

See *Genetech*, 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

In the present case Applicant has no possession of the subject matter of claim 1 and its dependent claims including the for method of treatment of oncoses, uncontrolled proliferation, sarcoma, acute lymphatic leukemia (ALL) acute promyleotic leukemia (APL) Hodgkin's disease, lung carcinoma and many more by disorazole compounds of formula I as in claim 1. The specification provides test data for proliferation of three disorazole compounds A1, D1 and E1, the claims are too broad and disclosure does not provide guidance or direction for the treatment of all the diseases as claimed. Applicant has no possession of the claimed subject matter at the time the invention was made.

Applicant is kindly requested to explain this issue.

Table 1 on page 16 discloses the inhibition of proliferation by Disorazole E1, D1 and A1 according to the invention in the XTT cytotoxicity test on human cell lines (proliferation assay, EC50 in μ g/ml). Tables 2-4 and comparison with the reference compounds has been fully considered. There is no example to use the compound with another "antitumor agent" or signal transduction inhibitors".

See *In re Buting*, 163 USPQ 689. The disclosure provides no indication of whether the compounds treat all cancers. To make clearer the lack of enablement for treatment of all cancer, extrinsic evidence is supplied by Draetta (Ann. Reports Med.

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Chem.), Draetta et al. in "Annual Reports in Medicinal Chemistry", 1996, Academic Press, San Diego, pp 241-246, final sentence on page 246 although many still think about the need for a magic bullet as a cure for all cancers, our knowledge of the molecular mechanism underlying this disease make the prospect of developing such a universal cure very unlikely." Since no universal cure for cancer has been developed, it follows that there is no correlation between the assays relied upon by applicants and the ability to treat all types of diseases base on rapid and uncontrolled proliferation of endogenous cells. Thus, the data as presented are not sufficient to enable such claims.

Further, in the art of clinical oncology, no compound has yet shown clinical efficacy against every type of cancer. Different agents are used for different forms of cancer and no single agent is listed as a treatment of every single type of cancer. Balasubramanian reference (Recent Developments in Cancer Cytotoxics) on page 151 first paragraph "the successful treatment of solid tumors remains a formidable challenge." There is no teaching as to how the claimed compound(s) for the "treatment of a disease in humans or animals which is based on rapid and uncontrolled proliferation of endogeneous cells comprising administering the compound of claim 1 to a human or animal in need of such a treatment". (claim 5). The treatment of oncoses, uncontrolled proliferation, sarcoma, acute lymphatic leukemia (ALL) acute promyleotic leukemia (APL) Hodgkin's disease, lung carcinoma and many more by disorazole compounds of formula I as in claim 1 is not predictable. The specification provides test data for proliferation of three disorazole compounds A1, D1 and E1, Since there is no guidance and/or direction provided by the Applicants for method of treatment of

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oncoses, uncontrolled proliferation, sarcoma, acute lymphatic leukemia (ALL) acute promyleotic leukemia (APL) Hodgkin's disease, lung carcinoma and many more by disorazole compounds of formula I as in claim 1 one skilled in the art would not be able to make and use the invention.

The specification provides test data for proliferation of three disorazole compounds A1, D1 and E1, the claims are too broad and disclosure does not provide guidance or direction for the treatment of all the diseases as claimed. See MPEP 2163.06.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

Response to Remarks

Claims are amended therefore rejection under 35 U.S.C. 102(b) as being anticipated by JANSEN et al. (Liebig Ann. Chem. (1994), 759-773) (See disarozole compound 19-21 on page 765, same compounds was claimed in present invention).

Claims are amended therefore rejection under 35 U.S.C. 102(b) as being anticipated by IRSCHIK et al., (The J. of Antibiotics See Fig. 1 and Table 1 on page 31).

Claims are amended therefore rejection rejected under 35 U.S.C. 112, first paragraph scope of enablement rejection is withdrawn. The reference BELIKOV

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provided as exhibits is not considered at this time because it is not in English. Applicant is requested to provide a copy of translation if that is easily available to them or provide an English abstract.

New matter rejection is withdrawn because claims are amended.

Written description rejection is maintained because arguments are not found persuasive. The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983).

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER